February 8, 2021

MEDRAD, Inc.
Mike Burnside
Manager
9055 Evergreen Blvd NW
Minneapolis, Minnesota 55433-8003

Re: K113428
Trade/Device Name: AngioJet Ultra DVX Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Mike Burnside:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 02, 2011. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.02.08 08:09:07 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2011

MEDRAD, Inc.
c/o Mike Burnside
Manager, Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K113428
Trade/Device Name: Angiojet Ultra DVX Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: November 18, 2011
Received: November 21, 2011

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K113428

Device Name: AngioJet® Ultra DVX® Thrombectomy Set

Indications for Use:

The AngioJet Ultra DVX Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from :

- upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
- upper extremity peripheral veins ≥ 3.0mm in diameter,
- ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
- A-V access conduits ≥ 3.0mm in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113428

K113428

DEC - 2 2011

Section 5 – 510(k) Summary

Submitter:
MEDRAD, Inc.
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003 USA

Contact Person:
Mike Burnside
Manager, Regulatory Affairs
Phone: (763) 717.1077
Fax: (763) 780.2227
Email: XXXX

Date Prepared:
November 18, 2011

Trade Name:
AngioJet® Ultra DVX® Thrombectomy Set

Classification:
870.5150 and 870.1210

Product Code:
DXE and KRA

Predicate Device(s):
The subject device is equivalent to the following devices:
- K091593 AngioJet Ultra DVX Thrombectomy Set
- K101406 AngioJet Solent Proxi Thrombectomy Set

Device Description:
AngioJet Ultra DVX Thrombectomy Set is a sterile, single use, disposable set that includes a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra DVX Thrombectomy Set is used with the AngioJet Ultra Console.

Intended Use:
The AngioJet Ultra DVX Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
- upper extremity peripheral veins ≥ 3.0mm in diameter,
- ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
- A-V access conduits ≥ 3.0mm in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Comparison to predicate:
Design changes were made to the distal section of the AngioJet Ultra DVX device to make the device more robust to guide wire use.

Performance Data:
Bench testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:
- Catheter operational characteristics
- Leak testing

- Guide wire compatibility tests
- Tracking
- Extended use
- Hemolysis ratio
- Distal emboli
- Catheter tip temperature
- Mechanical integrity (tensile strengths, compression / buckling, torque testing)

Conclusion: MEDRAD considers the AngioJet Ultra DVX Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.